U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT OAR-06-01, OBSERVATION AUDIT OF U.S. DEPARTMENT OF ENERGY, OFFICE OF ENVIRONMENTAL MANAGEMENT AND OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, AUDIT 06-DOE-AU-001 FOR THE SAVANNAH RIVER OPERATIONS OFFICE, SAVANNAH RIVER NATIONAL LABORATORY, PLUTONIUM VITRIFICATION PROJECT

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1.0 INTRODUCTION

On December 5–8, 2005, staff from the U.S. Nuclear Regulatory Commission (NRC), Division of High-Level Waste Repository Safety, observed the U.S. Department of Energy (DOE), Office of Environmental Management (EM) and Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Audit 06-DOE-AU-001 of the DOE Savannah River Operations Office, Savannah River National Laboratory (SRNL), Plutonium Vitrification Project (PVP). The EM/OCRWM joint audit was conducted of SRNL's PVP activities that will provide input to the planned Yucca Mountain Repository license application (LA). The PVP is intended to develop a vitrified waste form for disposal of contaminated plutonium (Pu) waste. The audit was to evaluate the adequacy and effectiveness of the implementation of the SRNL quality assurance (QA) requirements in compliance with the requirements of DOE/RW-0333P, Revision 16, Quality Assurance Requirements and Description (QARD), for the PVP testing and data generation activities. The NRC observers assessed the effectiveness of the DOE audit team and the audit process in achieving the audit objective.

2.0 MANAGEMENT SUMMARY

The DOE conducted an EM/OCRWM joint audit of SRNL's PVP activities for development and testing of a vitrified plutonium waste form, to provide data for input to the planned Yucca Mountain Repository license application (LA). The PVP activities were at an early stage with some preliminary glass compositions prepared and leaching, dissolution, and microstructural examination and testing beginning. In relation to technical performance, the audit team examined design documents to determine the effectiveness of OCRWM design control measures. Implementation of various programmatic elements in DOE's QARD as well as technical areas related to the Pu disposition in high level waste glass were assessed by DOE. The objectives of this audit were to evaluate (i) the adequacy, implementation, and effectiveness of applicable QA requirements; and (ii) data quality and test plans related to the Pu glass testing program. The audit team determined that SRNL was effectively implementing its QA program commitments. In addition, the audit team identified four minor adverse conditions and two opportunities for improvement. The audit team concluded that, overall, the QA requirements were being effectively implemented and PVP QA, technical and project documents were satisfactory.

The observers reviewed the qualifications of the audit team leader, auditors, and technical specialist and determined that they were qualified by education, experience, and training and were independent of the areas reviewed. The observers determined that the audit was performed effectively and agreed with the audit team's conclusions and findings. However, the observers determined that the audit may have been performed more efficiently with additional planning and coordination of the auditor and technical specialist audit activities.

3.0 PARTICIPANTS

DOE Audit Team

Duli Agarwal, Audit Team Leader (ATL)
Carl Weber, ATL in training
Denis Koutsandreas, Auditor
James Flaherty, Auditor
Robert Toro, Auditor
Chung-King Liu, Technical Specialist

NRC Observers

Wilkins Smith, Observation Team Leader, NRC
Tae Ahn, Technical Specialist, NRC
Albert Wong, Technical Specialist, NRC

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The audit team conducted the audit in accordance with the QARD as implemented by Administrative Procedure (AP)–18.4Q, DOE EM/RW Oversight Process, and Line Procedure (LP)–16.2Q–OCRWM, Management of Conditions Adverse to Quality for External Organizations. The observers followed NRC Manual Chapter 2410, Conduct of Observation Audits, while observing the audit.

4.1 Scope of the Audit

The audit team evaluated the adequacy, implementation, and effectiveness of applicable requirements and project planning, QA, and testing records and documents relating to the PVP, including Task Technical & Quality Assurance Plans (TTPs). The audit team evaluated SRNL's implementation in relation to the QARD, SRNL DOE/RW-0333P Matrix, SRTC-QAE-2001-0020, Revision 11, WSRC-RP-92-225, QA Management Plan, Revision 13, and current site implementing procedures.

4.2 Conduct and Timing of the Audit

The observers determined that the audit team conducted the audit effectively. Prior to the start of the audit, the auditors prepared checklists based on applicable procedure requirements and applied the checklists to their assessments. When appropriate, the auditors and technical specialist went beyond the scope of their checklists to probe and resolve potential issues. However, the audit team's technical specialist and auditors had not coordinated their audit conduct planning prior to the audit. With the early stage of the project and limited activities, this lack of coordination initially led to inefficiencies and overlapping efforts. This matter was resolved and the audit was completed in an effective and efficient manner. At the time of the audit, no deficiencies or corrective actions had been issued on the PVP.

The audit was scheduled to evaluate the QA program planning and implementation early in the project activities so that any issues could be resolved early in the process so as to not impact the project quality. This audit was timely in that it was appropriate in relation to the planned project activities. Although there were limited actual test glass activities, testing, or test data available to audit, the QA planning, including the TTPs, were in place, and the controls applicable to this phase of development were properly assessed.

4.3 Audit Team Qualifications and Independence

The observers reviewed the qualifications of the audit team leader, auditors, and technical specialists, and determined that they were qualified by education, experience, and training and independent of the areas reviewed. The audit team had members with appropriate education and experience, so they were able to add performance-based components to their evaluations.

4.4 Examination of Quality Assurance Elements

4.4.1 Organization

The auditors reviewed the SRNL organization and the DOE SRO and WSRC interfaces that are applicable to the PVP activities. The applicable procedures were reviewed and their implementation discussed with cognizant staff and senior management.

In 2005, the SRNL organization transitioned from the Savannah River Technology Center to the national laboratory. The auditors noted that there was no controlled document that describes the SRNL organization structure including internal and external interfaces as required by Section 1.2 of the QARD. The current procedure L1-102, Revisions 5, SRTC Organization, describes the FRTC organizational structure as indicated by the SRNL DOE/RW-0333P Requirements Implementation Index. The audit team planned to issue a condition report (CR) on this issue but did not identify a performance issue on the PVP activities related to this issue. The audit team concluded that, with that exception, the organizational interfaces, requirements, and responsibilities were adequately implemented and functioning properly for the PVP.

4.4.2 Quality Assurance Program

The audit team evaluated the adequacy and implementation of QA program requirements for the PVP activities, including the documented flowdown of requirements in the SRNL DOE/RW-0333P Matrix, SRTCQAE-2001-00020, Revision 11, the WSRC-RP-92-225, QA Management Plan, Revision 13, WERC and SRNL implementing procedures listed in the QA Manual 1Q, the QARD matrix, and the SRNL Procedures Manual L1. TTPs for each of the three PVP tasks were also reviewed. The audit team concluded that the QA program for the PVP activities was adequate and being effectively implemented.

4.4.3 Procurement Document Control and Purchased Items and Services

The auditors reviewed the control of procurement documents and procured items and services for the PVP. The only planned procurement activity is for evaluation, analysis and testing at Argonne National Laboratory (ANL) and Pacific Northwest National Laboratory (PNNL). The procurement documentation and planning for ANL and PNNL was reviewed and discussed with project and technical management.

The statements of work for the ANL and PNNL activities required that copies of all applicable laboratory procedures (technical and administrative) be submitted to SRNL for review and approval. At the suggestion of the observers, the auditors reviewed the documentation to verify that this had been accomplished. The project and technical managers stated that they had done this review during surveillance of the laboratories, however this was not documented in the surveillance report or elsewhere. The audit team planned to issue a CR to document and address this issue.

The audit team concluded that, with the exception noted above, the QA program in these areas was adequately implemented and functioning effectively for the PVP.

4.4.4 Implementing Documents and Document Control

The auditors identified controlled documents and checked for correct maintenance of the documents and for obsolete documents. The auditors interviewed supervisors and staff responsible for records processing, and records receipt, identification, verification, classification, and archive processes were evaluated. The auditors visited the records storage to confirm proper operations. The audit team concluded that the QA program in these areas was adequately implemented and functioning effectively for the PVP.

4.4.5 Control of Measuring and Testing Equipment

The observers accompanied auditors through various laboratory and support areas to review the control of measuring and testing equipment (M&TE) used by SRNL for the PDP. Out of the 24 pieces of M&TE, the majority of them were weight sets and balances. The audit process included (i) review of M&TE calibration records, (ii) interviewing M&TE users (i.e., lab technicians) on the use of such equipment, (iii) discussions with cognizant M&TE program coordinator on how to ensure only calibrated M&TE were used in the PDP, and (iv) witnessing mock M&TE calibrations by the Savannah River Standards Laboratory (part of the SRNL).

The auditor identified one potential condition adverse to quality for which they planned to issue a CR. SRNL personnel uses two oven furnaces to prepare the non-radioactive glass samples. Prior to use, the oven furnace functional check procedure requires the lab technician to record the furnace temperature readouts from a calibrated thermocouple and the furnace temperature display. The lab technician then hands both temperature readings to the cognizant glass scientist to make a decision as to whether the furnace can be used to prepare the glass samples or not. The procedure itself does not list acceptance criteria for the lab technician to determine if the oven furnace is functional or not. The auditors believed this condition did not meet the DOE QARD Section 5.2.2.D, which specifies that quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished be established. The SRNL cognizant scientist acknowledged the auditor's finding as a potential area for improvement.

The auditor also discovered that an out-of-calibration sheet was inadvertently left out from a weight calibration package. Laboratory practice calls for an out-of-calibration cover sheet be placed with an out-of-calibration M&TE until the M&TE can be brought back to calibration. The SRNL cognizant M&TE point of contact acknowledged this human error, and it was identified as an isolated incidence.

Overall, the auditor was thorough and methodical in following the lines of inquiries prepared by the audit team before the audit. The audit team did not identify any programmatic deficiencies in this area, and concluded that the QA program requirements were adequate and effectively implemented in this area.

4.4.6 Handling, Storage and Shipping

An observer accompanied an auditor to review selective portions of the SRNL's radioactive material shipping program pertaining to the PDP. The audit process included (i) review of different shipping packages for labeling and marking, (ii) review of radioactive material

transportation, handling, and storage procedures, and (iii) discussions on various aspects of shipping, including the use of special equipment for lifting. The DOE auditor recommended a procedure be revised so the operator could record the tamper indicator device number on the procedure. The SRNL cognizant program manager readily acknowledged the suggestion.

Overall, the auditor closely followed the lines of inquiries prepared by the audit team. The audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate and effectively implemented in this area.

4.4.7 Nonconformances and Corrective Actions

The auditors determined that no nonconformances had been issued on the PVP as of the audit. Nor had any corrective actions been required or conducted. The auditors reviewed the implementing procedures in these areas, and noted that the process for inter-organizational Nonconformance Reports (NCRs) did not require inclusion of the NCR initiator in the closure of the NCR. The audit team recommended that the initiator be included in the closure process or notified of the disposition. The audit team also noted that nonconformances across the SRNL projects activities were not analyzed for quality trends. A CR documenting this issue was planned.

The audit team concluded that, except as noted above, the QA program requirements were adequate in these areas.

4.4.8 QA Records

The auditors reviewed the implementing procedures for records. The audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

4.4.9 Audits

The auditors reviewed the implementing procedures and sampled records for audits. Discussions with staff and management were held on audit implementation and self assessments. Two minor discrepancies were noted by the audit team and were being considered for documentation on CRs. One was SRNL Audit 2005-AR-11-00002, where there was no objective evidence of QARD orientation being completed for a technical specialist on the audit contrary to the requirements of the QARD. The other was for an incorrect reference on an audit finding and was corrected during this audit.

The audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

4.4.10 Sample Control and Scientific Investigation

The auditors reviewed the implementing procedures and project planning documents including the three task TTPs for PVP sample control and scientific investigations. Discussions were held with the project technical staff and managers, and laboratory logs and scientific notebooks were examined for sample control identification and traceability and proper documentation of the scientific investigations.

The audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

4.5 Examination of Technical Elements

4.5.1 Formulation and Testing of Pu glass

The auditors and technical specialist reviewed Pu glass testings in three areas:

(1) Leaching;
(2) Formulation; and
(3) Determination of Macroscopic Surface Area

The audit process included (i) reviews of various related test plans and QA procedures, (ii) assurance of data qualification in selected areas, and (iii) discussions on:

(1) Dissolution rate data and the fate of plutonium oxide and the neutron absorbers during the leaching process; and
(2) Sampling procedures in scientific log book.

The audit team technical specialist noted that the TTP and other PVP project plans did not include data quality objectives or planning and the audit team recommended that this be done, as follows:.SRNL PVP should describe data quality for chemical analysis and testing in the specific Task & Quality Assurance Plan. Current Analytical Study Plan, WSRC-RP-2005-01759, Revision 0, dated August 22, 2005, describes key data needs, including radiochemical data. Data quality (precision, accuracy, detection limit) should be identified before analysis is requested, and tracked during analysis to ensure quality of the data generated.

The audit team technical specialist, except for the recommendation for data quality, found the activities and planning for glass formulation and testing to be adequate.

The observers discussed the TTP and technical issues with the PVP project and technical managers. The observers noted that technical communication and coordination between the SRNL PVP managers and Yucca Mountain Project counterparts appeared to be working well. The observers also noted that the planned PVP studies included the formation of plutonium colloids in the waste glass form during long term storage.

4.6 Potential Audit Findings

The DOE audit team identified the following potential CRs:

1. No controlled document that describes the SRNL organization structure;
2. Lack of documentation of submittal, review and approval of contractor procedures.
3 Quantitative or qualitative acceptance criteria not documented.
4. Nonconformances trended not analyzed.
5. No documentation of audit technical specialist training.
6. Audit report noted wrong reference.

The audit team identified two recommendations:

1. The PVP planning documents for the plutonium glass testing should address data quality objectives and identify data quality requirements (precision, accuracy, detection limit) before analysis is requested, and data quality should be tracked during analysis.

2. The nonconformance report closeout process should include the issuer or the issuer should be notified of the disposition.

5.0 NRC STAFF FINDINGS

The observers determined that the audit team's auditors and technical specialist were effective in evaluating the QA program adequacy and the SRNL implementation of the applicable procedures as applied to PVP activities. The NRC technical observers noted that the formation of Pu colloids during long term storage of the glass waste form is under study by SRNL and appears to be risk significant for potential Yucca Mountain Repository. NRC plans to follow up issues associated with colloid formation in other technical communications with DOE.

5.1 NRC Observation Summary

The observers determined that the audit team was effective in evaluating the QA program adequacy and the SRNL implementation of applicable implementing procedures as applied to the PVP activities. The observers agreed with the audit team's conclusions, findings, and recommendations. The observers determined that the audit team members were qualified, independent of the areas being audited, and had adequate knowledge and understanding of the requirements.

The observers determined that the audit process could be improved by better planning and coordination of joint audit activities by the auditors and technical specialists.

5.2 NRC Audit Observer Inquiry

No audit observer inquiries were submitted.